In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-839V

Filed: July 22, 2025

* * * * * * * * * * * * *
MARY MICELI, *
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Petitioner, *
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v. *
*
SECRETARY OF HEALTH *
AND HUMAN SERVICES, *
*
Respondent. *
* * * * * * * * * * * * *

Laura Levenberg, Esq., Muller Brazil, Dresher, PA, for petitioner.
Emilie Williams, Esq., U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

Roth, Special Master:

On June 13, 2018, Mary Miceli ("petitioner") filed a petition pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 *et seq.*[2] ("Vaccine Act" or "the Program"). Petitioner alleged that the influenza ("flu") vaccination she received on October 28, 2016 resulted in a left shoulder injury related to vaccine administration ("SIRVA"). Petition, ECF No. 1.

Having considered the entire record in this case, I find petitioner has not provided preponderant evidence of causation. As discussed in more detail below, the claim does not meet the Table requirements for a SIRVA claim, and petitioner neither argued nor provided evidence to support of an off-Table claim.

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[1] Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned finds that the identified material fits within this definition, such material will be redacted from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

I. Relevant Procedural History

The Ruling on Onset, which was issued on October 31, 2022, contains a full recital of the procedural history and facts in this matter and is incorporated herein by reference. Onset Ruling, ECF No. 51. For purposes of this decision, a condensed procedural history is provided below.

The petition, petitioner's affidavit, witness affidavits, and medical records were filed on June 13, 2018. Petition, ECF No. 1; Petitioner's Exhibits ("Pet. Ex.") 1-12, ECF No. 1. Additional medical records were filed on September 28, 2018, October 4, 2018, April 12, 2019, and May 15, 2019. Pet. Ex. 13, ECF No. 9; Pet. Ex. 14-15, ECF No. 11; Pet. Ex. 16, ECF No. 19; Pet. Ex. 17, ECF No. 20.

In his Rule 4(c) Report filed on June 7, 2019, respondent recommended against compensation, submitting that petitioner failed to satisfy the criteria for a Table SIRVA injury. Respondent's Report ("Resp. Rpt.") at 6, ECF No. 21. Specifically, petitioner's medical records did not support onset within 48 hours of vaccination, and she had a preexisting history of diffuse osteoarthritis that could explain her symptoms. *Id.* at 6-7. Respondent also noted that petitioner had not provided evidence to establish causation-in-fact. *Id.* at 7-9.

The matter was reassigned to the undersigned and an initial status conference was held, after which petitioner was ordered to file petitioner's worker's compensation denial information and transcriptions of illegible records prepared by her physician. The parties were also ordered to provide a mutually agreeable date for an onset hearing. ECF No. 25. Petitioner filed the requested exhibits on August 27, 2019, September 23, 2019, September 26, 2019, and October 9, 2019. Pet. Ex. 18, ECF No. 31; Pet. Ex. 19, ECF No. 32; Pet. Ex. 20, ECF No. 33; Pet. Ex. 21, ECF No. 34.

An onset hearing was held on September 10, 2020 via WebEx videoconferencing. After the hearing, petitioner was ordered to file additional records. The records were filed on September 24, 2020. ECF No. 43; Pet. Ex. 22-27, ECF No. 44. On October 26, 2020, respondent filed a status report advising that he was satisfied that the record was complete. ECF No. 48.

After considering the evidentiary record as a whole, I determined that the onset of petitioner's "left arm/shoulder pain" was in March 2017, making this case a causation in fact case, not Table case. Onset Ruling, ECF No. 51. In lieu of an expert report, petitioner filed a Motion for Ruling on the Record on January 16, 2023. Motion, ECF No. 54. Respondent filed his response on March 22, 2023. Response, ECF No. 57. Petitioner did not file a reply.

I have determined that the parties have had a full and fair opportunity to present their cases and that it is appropriate to resolve this issue without a further hearing. See Vaccine Rule 8(d); Vaccine Rule 3(b)(2); *Kreizenbeck v. Sec'y of Health & Human Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020) (noting that "special masters must determine that the record is comprehensive and fully developed before ruling on the record."). The matter is now ripe for a ruling on entitlement.

II. Legal Standards for Entitlement

In general, to gain an award under the National Vaccine Injury Compensation Program, a petitioner must make several factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a causal link between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 13(a)(1)(A); § 11(c)(1)(C)(i); § 14(a); § 13(a)(1)(B).

Relevant to this case, the Vaccine Injury Table lists a Shoulder Injury Related to Vaccine Administration or "SIRVA" as a compensable injury if it occurs within 48 hours of vaccine administration. § 14(a), as amended by 42 CFR § 100.3. Table Injury cases are guided by regulatory "Qualifications and Aids in Interpretation" ("QAIs"), which provide a more detailed explanation of what should be considered when determining whether a petitioner has suffered an injury listed on the Vaccine Injury Table. 42 CFR § 100.3(c). To be considered a "Table SIRVA," petitioner must show that his injury fits within the following definition:

> SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis . . . . A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time-frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
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> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 CFR § 100.3(c)(10).

Alternatively, if no injury falling within the Table can be shown, the petitioner may still demonstrate entitlement to an award by showing that the vaccine recipient's injury was caused-in-fact by the vaccination in question. § 13(a)(1)(A); § 11(c)(1)(C)(ii). To so demonstrate, a petitioner must show that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). In particular, a petitioner must show by preponderant evidence: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury in order to prove causation-in-fact. *Althen v. Sec'y of Health & Human Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005).

For both Table and Non–Table claims, Vaccine Program petitioners must establish their claim by a "preponderance of the evidence". § 13(a). That is, a petitioner must present evidence sufficient to show "that the existence of a fact is more probable than its nonexistence . . . ." *Moberly*, 592 F.3d at 1322 n.2. Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). However, a petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 13(a)(1). Once a petitioner has established their *prima facie* case, the burden then shifts to respondent to prove, also by preponderant evidence, that the alleged injury was caused by a factor unrelated to vaccination. *Althen*, 418 F.3d at 1278 (citations omitted); § 13(a)(1)(B).

III. Factual Record

An in-depth, detailed review of the factual record is contained in the Ruling on Onset in this matter. Onset Ruling, ECF No. 51. However, the findings in that ruling bear repeating herein for purposes of entitlement. While that ruling only addressed onset, the conclusions were based on all the evidence filed, including the hearing testimony and an assessment of the credibility of the witnesses who submitted affirmations and testified. I found that while the petitioner was candid and credible, her witnesses were not. *Id*. at 24.

The medical records, affidavits, testimony and other evidence filed supported the following:

1. Petitioner received a flu vaccine on October 28, 2016 that felt "different." She did not have pain, just soreness, "hurtness", and weakness, an indication that something was different. Tr. 46, 67, 131-34.

2. On November 7, 2016, petitioner presented to Dr. Resnick[3] with pain in her right foot, later determined by MRI to be a tear in the right plantar fascia. Petitioner suffered "severe pain" in her foot until about March 11, 2017, when she reported improvement of the plantar fasciitis to Dr. Resnick. She still had generalized pain in her feet. Pet. Ex. 20 at 5.

3. Between November 5, 2016 and March 11, 2017, petitioner attended 13 medical visits including physical therapy without mentioning any left arm or shoulder pain. *See generally* Pet. Ex. 20; Pet. Ex. 5; Pet. Ex. 6 at 22-23; Pet. Ex. 8 at 7-8.

4. On April 10, 2017, petitioner presented for an annual employment health assessment and reported for the first time that she suffered an "arm injury since flu vaccine Oct '16." Pet. Ex. 2 at 58. She reported worsening pain. *Id*. at 13.

5. On April 18, 2017, petitioner presented to Dr. Sherman, who had previously treated her for hip pain, knee pain, and osteoporosis in 2015. Pet. Ex. 21 at 7, 10; Pet. Ex. 3 at 14, 15-20. Dr. Sherman conducted an examination on behalf of worker's compensation which revealed forward flexion and abduction of 170 degrees, external rotation of 60 degrees, and positive impingement sign. There was no AC joint tenderness or instability. There was 5/5 strength in all planes. His impression was "Right (sic) shoulder impingement syndrome."[4] Pet. Ex. 21 at 7; Pet. Ex. 3 at 14. He ordered physical therapy and Mobic[5] with possible subacromial injection if symptoms persisted. *Id*.

6. Petitioner returned to Dr. Sherman on May 6, 2017 with continued "discomfort" but was "somewhat better." She refused subacromial injection and was treated with Mobic. Pet. Ex. 21 at 8.

7. At her May 6, 2017 routine visit with Dr. Resnick for generalized foot pain, petitioner advised Dr. Resnick for the first time of a left shoulder flu shot reaction. Pet. Ex. 20 at 5.

8. Petitioner presented to physical therapy for her left arm/shoulder on May 16, 2017, one month after seeing Dr. Sherman, and reported left shoulder pain of 9/10. Her passive range of motion on abduction was now 102 degrees, a dramatic difference from the 170 degrees a month earlier. Pet. Ex. 5 at 4, 6.

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[3] Petitioner saw Dr. Resnick, a podiatrist, for years prior to her vaccination to treat pain in her feet that included degenerative joint disease, bursectomy, hammertoes, and metatarsophalangeal joint pain that required her to wear sneakers, orthotics, and a right ankle brace. *See generally* Pet. Ex. 15; Pet. Ex. 20.

[4] Impingement syndrome is "a type of overuse injury with progressive pathologic changes resulting from mechanical impingement by the acromion, coracoacromial ligament, coracoid process, or acromioclavicular joint against the rotator cuff; changes may include reversible edema and hemorrhage, fibrosis, tendinitis, pain, bone spur formation, and tendon rupture." *Impingement syndrome*, DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1804 (33rd ed. 2019) [hereinafter DORLAND'S].

[5] Mobic is a trademark name for meloxicam. *Mobic*, DORLAND'S 1154. Meloxicam is a nonsteroidal anti-inflammatory drug used in the treatment of osteoarthritis. *Meloxicam*, DORLAND'S 1111.

9. Between May 16, 2017 and June 26, 2017, petitioner attended physical therapy nine times with complaints of pain radiating from her left shoulder into the upper arm and hand, pain at the deltoid, limitation of motion on abduction, and clicking of her left shoulder. Pet. Ex. 5 at 4. At her June 26, 2017 appointment, she mentioned difficulty dressing secondary to pain and range of motion of the left shoulder. *Id*. at 5. Petitioner did not complain of difficulty driving or attending to her duties at work.

10. At her June 26, 2017 visit with Dr. Kelly for hypertension and diffuse aching joint pain, petitioner reported aching left shoulder pain that was gradual in onset and moderately limiting her activities. She reported being unable to sleep on her left side due to left shoulder pain since her flu shot that was "getting worse". Pet. Ex. 6 at 25. She had tenderness of the glenohumeral joint, acromioclavicular joint, and bicipital groove on examination. There was crepitus and pain with abduction and adduction of the left shoulder. Pet. Ex. 6 at 27.

11. Petitioner underwent an MRI of the left shoulder on July 5, 2017, which revealed complete full thickness supraspinatus[6] tendon tear with proximal tendon retraction to the level of the acromioclavicular joint with mild fatty replacement muscle; full thickness tear of the anterior two thirds of the infraspinatus[7] with proximal tendon retraction to the level of the acromion; high grade partial thickness articular sided tear of the posterior third of the infraspinatus; and subscapularis[8] tendinosis[9] with superior articular sided fibers fraying. Pet. Ex. 8 at 5. The findings were consistent with subacute/chronic Hill-Sachs impaction fracture[10] deformity and bony Bankart Lesion.[11] There was large glenohumeral joint effusion/synovitis[12] with free communication to the subacromial bursa[13] via the full thickness rotator cuff tears and acromioclavicular joint osteoarthritis. The findings were suggestive of a near full-thickness avulsion tear[14] of the long head of the biceps from the glenoid insertion with proximal tendon retraction into the mid- to distal arm. *Id*.

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[6] The supraspinatus is a muscle that runs from the supraspinous fossa of the scapula to the greater tubercle of the humerus and abducts the humerus. *Supraspinatus*, DORLAND'S 1195.

[7] The infraspinatus is a muscle that runs from the infraspinous fossa of the scapula to the greater tubercle of the humerus and rotates the humerus laterally. *Infraspinatus*, DORLAND'S 1189.

[8] The subscapularis is a muscle that runs from the subscapular fossa of the scapula to the lesser tubercle of the humerus and rotates the humerus medially. *Subscapularis*, DORLAND'S 1194.

[9] Tendinosis refers to any pathologic condition of a tendon. *Tendinosis*, DORLAND'S 1852.

[10] A Hill-Sachs lesion is a "compression fracture of the posteromedial humeral head, sometimes occurring with anterior dislocation of the shoulder, caused by impaction of the humeral head on the anterior rim of the glenoid fossa." *Hill-Sachs lesion*, DORLAND'S 1012.

[11] A Bankart lesion is the avulsion of the anterior glenoid labrum following anterior dislocation of the shoulder. *Bankart lesion*, DORLAND'S 1011.

[12] Effusion is the escape of fluid into a part or tissue. *Synovitis*, DORLAND'S 589. Synovitis is "inflammation of a synovial membrane; it is usually painful, particularly on motion, and is characterized by a fluctuating swelling due to effusion within in synovial sac." *Effusion*, DORLAND'S 1826.

[13] The subacromial bursa is "a bursa located between the acromion and the insertion of the supraspinatus muscle, extending between the deltoid and the greater tubercle of the humerus". *Subacromial bursa*, DORLAND'S 259.

[14] Avulsion is the ripping or tearing away of a part either accidentally or surgically. *Avulsion*, DORLAND'S 81.

12. Dr. Sherman discussed the MRI results with petitioner on July 19, 2017. His impression was an "irreparable rotator cuff tear." An injection was administered. Pet. Ex. 21 at 6.

13. Petitioner continued attending physical therapy in July and August 2017. Her pain was reduced to a reported 5/10 and her range of motion increased to 130 degrees. She continued to express difficulty with dressing, intermittent clicking of the left shoulder, and pain from her left shoulder into the upper arm and hand with left bicep strength of 3+/5. Pet. Ex. 5 at 5. Petitioner did not report any difficulty in driving or attending to her duties at work.

14. At a visit with Dr. Sherman on August 16, 2017, petitioner reported that she was "quite happy" and doing better since the shoulder injection. She had full range of motion and 4/5 strength on the left. She was to continue with rotator cuff scapular training and consider arthroscopy with debridement if her symptoms worsened. Pet. Ex. 21 at 5.

15. Petitioner returned to Dr. Sherman nine months later, on May 16, 2018, with increasing shoulder pain for several months and with sleep. She noticed noises in her shoulder. On examination, she had positive impingement, forward flexion of 180 degrees, abduction of 180 degrees with 4/5 strength, internal rotation that lacked two spinal levels with 5/5 strength, and external rotation was 30 degrees with 3/5 strength. Dr. Sherman's impression was left shoulder rotator cuff insufficiency. A subacromial injection was given. Pet. Ex. 21 at 9.

16. Petitioner described her receipt of the October 28, 2016 flu vaccine as, "… soreness, a hurtness, a – you know, an indication that something was different." Tr. 43-44, 46. "Right after the flu shot, I had soreness… the weakness started maybe within a few days. The soreness continued and got more sore. I didn't pay much attention to it…But the weakness was – the weakness and the soreness was there…almost from the beginning, yeah." Tr. 65. "Maybe that day, the next day, that week…the weakness was starting, soreness and weakness until it progressed to the lack of mobility and severe pain which was months later". Tr. 67. Petitioner admitted it was not pain but soreness and weakness that continued until the weakness prevented her from lifting her arm up to drive, though she could not recall when that began. Tr. 133-34. She conceded she had no concerns or need to call a doctor about her left arm until months later. Tr. 131-34.

17. The progression of her left arm/shoulder injury was gradual. Tr. 47-49. Between November 5, 2016 and March 11, 2017, the pain from her plantar fasciitis was incapacitating and made it difficult to walk. Tr. 52, 122-23; Pet. Ex. 9 at 1. During this time, she was unconcerned about her left arm and "something, which I still thought was a flu shot reaction, but didn't pay much attention to it…but it was always there still, that left arm pain." Tr. 68-69. "I was not debilitated from the arm right after the flu shot. It was just in soreness and weakness." She was not concerned until some point in February or March. Tr. 131-32.

18. Petitioner developed "pain" in her left arm and shoulder that caused difficulty in sleeping, driving, and attending to her daily activities in March 2017. Tr. 62-63, 133-34. Then, between March and July 2017, the severity of her shoulder pain increased and worsened over a short period of time, which was alarming and prompted her to seek medical care. Tr. 47-50, 59, 62, 126-27. Petitioner conceded it was at this point that she had pain which she had not previously experienced in her left arm. Tr. 47-50, 58-59, 60-64, 67, 115-16, 125-27.

19. Petitioner did not recall where on her left arm she received the October 28, 2016 flu vaccine or where on her arm she had pain. Tr. 43, 95.

20. Petitioner's coworkers helped her prior to the October 28, 2016 flu vaccine due to the longstanding debility of her right hand, but she did not seek anyone's assistance at work, use a cart for her charts, or seek medical care until March or April 2017 when she developed severe arm pain. Tr. 62, 125, 127, 131-34. She was never "debilitated" by her left arm and is unsure where that term came from. Tr. 131.

21. Petitioner agreed that she had 13 visits with medical providers between November 5, 2016 and April 10, 2017 and did not mention any left arm/shoulder pain. Tr. 53-55, 115-16.

22. Petitioner first conducted Google searches on March 28, 2017, March 30, 2017, and April 2, 2017 on arm/shoulder injuries and flu vaccines and discovered the Vaccine Program, the Vaccine Court, and details about arm/shoulder injury associated with the flu vaccine. Tr. 69-70; Pet. Ex. 22. She also downloaded and filled out a VAERS report that she never filed but her attorneys did. Tr. 75-76; Pet. Ex. 18 at 2.

23. Petitioner reported her left arm/shoulder injury at her annual work examination with Employee Health on April 10, 2017, because someone suggested she report it. Tr. 75; Pet. Ex. 1. She also asked for her vaccine record because she knew she would need proof of vaccination. Tr. 75.

24. Ms. Somma placed petitioner's onset of "extreme pain," inability to dress herself, drive, carry charts, or open doors on the date of the vaccine, October 28, 2016, and on October 31, 2016. Tr. 7-12, Pet. Ex. 12 at 1-2. Ms. Somma stated petitioner needed assistance with her charts for quite some time but did not recall petitioner having any difficulties with tasks prior to October 2016. Tr. 18.

25. Mr. Sinclair stated the onset of petitioner's pain was "immediately after receiving the vaccine" and he spoke to her about her severe discomfort and limited strength in her left arm, increasing pain, limited range of motion, difficulty driving, and need for assistance on October 31, 2016. Tr. 137-140, 153; Pet. Ex. 10 at 1. Mr. Sinclair recalled petitioner using a cart for her charts after that, in 2016, because she was struggling. Tr. 144-45. According to Mr. Sinclair, petitioner "complained for at least 6 months of shoulder pain with no improvement" and he assisted her during this time and until he

transferred to another unit in 2018. Tr. 159. He never had to assist her prior to October 2016. Tr. 147.

26. Ms. Cannatelli affirmed that petitioner's onset of pain was immediately upon receipt of the vaccine, that petitioner guarded her arm and was unable to raise her arm above her waist on the day of the vaccination. Pet. Ex. 11 at 1. Ms. Cannatelli discussed this with petitioner on both the day of the vaccine and on October 31, 2016. Tr. 164-65, 173. She assisted petitioner with charts prior to October 2016, but petitioner never struggled prior to October 2016. Tr. 168-69, 177, 180. According to Ms. Cannatelli, when days became weeks, she urged petitioner to go to the doctor and report the injury. Tr. 170-71, 183-84. Initially, Ms. Cannatelli stated that petitioner saw a doctor and brought in reports and scans but could not remember when that occurred. Tr. 171. She then "vaguely" remembered petitioner going to the doctor around Thanksgiving because she was getting worse. Tr. 174. Ms. Cannatelli then stated she asked if petitioner went to the doctor, but petitioner said no, so she just left it alone because they are only co-workers. Tr. 183-84.

27. Ms. Cannatelli then stated she saw petitioner daily between October 2016 and 2017, but only spoke to her briefly about twice a week until petitioner started to go to the doctor but could not recall when that was. Tr. 174-75. Ms. Cannatelli did not recall petitioner mentioning an onset of significantly worsening pain which prompted her to see a doctor or that she did not see a doctor for her left arm/shoulder until April 2017. Tr. 186.

28. Petitioner's witnesses were less informed about her foot issues: Ms. Somma recalled petitioner having a foot problem at the same time as her shoulder causing her stress and affecting her work and life in general. Tr. 16-17, 20; Pet. Ex. 12 at 2. Mr. Sinclair believed petitioner's foot problem was after her shoulder injury, but she did not complain of pain, only moved slowly. Tr. 148. Once prompted by counsel, he recalled her wearing a boot after October 2016 but could not recall if she was still wearing it when he left the unit in 2018. Tr. 157. Ms. Cannatelli stated petitioner had "some fasciitis" in September that pre-existed her vaccine and shoulder injury. Tr. 172, 187-88. She recalled that petitioner wore a boot for a while but stopped wearing it around the same time as the flu vaccine. Tr. 181-82. Ms. Cannatelli did not recall petitioner having difficulties walking after the vaccine and through January 2017 and added her foot was not a topic of conversation. Tr. 182, 187.

As clearly demonstrated above, petitioner experienced an unusual feeling upon receipt of her flu vaccine on October 28, 2016, from which she "may have had" soreness, "hurtness", and the gradual onset of weakness of her arm. She had no pain or disability until sometime in March or April 2017, when she suffered a severe and abrupt onset of pain requiring medical attention. She consistently placed the location of that pain in her bicep, between her elbow and shoulder, which was shown to be ruptured on an MRI taken in July 2017. Contrary to the affirmations and testimony of her witnesses, petitioner denied that she suffered "debilitating" left arm pain that rendered her unable to lift her left arm, dress, drive, carry charts without assistance, or that she used a chair or cart immediately upon receipt of and following her vaccination on October 28,

2016. Tr. 131. The statements of petitioner's witnesses were contrary to and unsupportive of what petitioner testified to regarding the onset of her shoulder pain.

To her credit, petitioner did not attempt to change or challenge the record. She admitted that she did not seek any medical care for her left arm following her flu vaccine, because her arm was achy and sore, did not affect her activities of daily living and gradually became weak in the area between the elbow and shoulder. Tr. 58-59, 62-63. It was not until she suffered an abrupt onset of severe pain in "March or April 2017" that disrupted her sleep and daily activities that she required medical care for her left arm. Tr. 50, 58-59, 131.

IV. Parties' Arguments

A. Petitioner's Motion

Petitioner argued "that he (sic) has provided evidence that satisfies her burden of proof, establishing that she suffered a left shoulder injury related to vaccine administration ("SIRVA") caused by an influenza ("flu") vaccine on October 28, 2016, and is therefore entitled to compensation." Motion at 1, ECF No. 54.

Petitioner presented a brief summary of her medical history, which only included the receipt of the flu vaccine in her left shoulder on October 28, 2016, her first presentation for care of "worsening left shoulder pain since receipt of the flu vaccine" on April 10, 2017, and her subsequent visits for left shoulder pain. Motion at 2-4. She noted that an MRI on July 5, 2017 revealed a full thickness rotator cuff tear.[15] *Id*. at 3. Petitioner also submitted cursory summaries of her affidavit and testimony, as well as those of her coworkers Craig Sinclair, Colleen Cannatelli, and Susan Soma. *Id*. at 4-6.

Petitioner maintained that she has satisfied the requirements of a SIRVA resulting from her October 28, 2016 flu vaccine. Specifically, she argued that she did not have any injury to her left shoulder prior to October 28, 2016; she suffered symptoms within 48 hours of the vaccination; she had pain and reduced range of motion limited to her left shoulder; that there is no other condition or abnormality that would explain her symptoms; and that she suffered the residual effects of her shoulder injury for more than six months. Motion at 8-10.

Petitioner did not present any argument or evidence that she suffered an off-Table injury, only that she has satisfied the requirements for a Table SIRVA injury. *See* Motion at 7-8.

B. Respondent's Response

Respondent opposed petitioner's motion, relying on his position set forth in the Rule 4(c) Report and incorporating it by reference therein.[16] Response at 2, ECF No. 57. Respondent pointed to the contemporaneous medical records, showing that petitioner's shoulder pain "developed gradually sometime after vaccination, and were (sic) only significant enough to report nearly six

[15] Petitioner did not include the rest of the findings from the July 5, 2017 MRI. Pet. Ex. 8 at 4-5.

[16] In his Rule 4(c) Report, respondent recommended against compensation, submitting that petitioner's claim did not satisfy the criteria for a Table SIRVA. Resp. Rpt. at 6, ECF No. 21.

months post-vaccination." Resp. Rpt. at 6. Respondent argued that the Court's ruling on onset is well-supported by the contemporaneous medical records, noting that between the subject vaccination and her first report of shoulder pain, petitioner "attended eleven podiatry visits for complaints concerning her right foot, but never mentioned arm/shoulder pain." Response at 2.

Additionally, respondent noted that "petitioner had a preexisting history of diffuse osteoarthritis that could her explain her symptoms," and an MRI eight months post-vaccination "revealed many changes unrelated to an inflammatory reaction from vaccination, including osteoarthritis." Resp. Rpt. at 7. Finally, petitioner's first report of shoulder pain was nearly six months after vaccination and made in the context of litigation and a concurrently filed worker's compensation claim, which was denied. *Id*. at 9.

Respondent concluded there is not preponderant evidence to establish petitioner's entitlement to compensation for her alleged injury, because the contemporaneous medical records do not establish onset within 48 hours of her flu vaccine as reflected by the Court's ruling finding onset occurred in March 2017. Response at 2.

V. Analysis

Because I have already determined that the evidence presented in this case shows that petitioner did not suffer from "pain" in her left arm/shoulder until approximately five months post-vaccination in March 2017, petitioner is unable to satisfy the requirements for a Table SIRVA. Specifically, it was determined that she did not establish that her "pain occurred within the specific time frame", or within 48 hours of vaccination as required by the second QAI criterion. 42 C.F.R. § 100.3(c)(10)(ii). Thus, petitioner would only be entitled to compensation if she provided preponderant evidence of causation.

The Ruling on Onset provided an in-depth analysis of the evidence presented in this case but only addressed the second QAI criterion: the onset of petitioner's alleged pain. To be thorough, a brief discussion of the other QAI criteria is warranted.

A. Petitioner could satisfy part (i) but not parts (iii) or (iv) of the SIRVA QAI criteria.

The first criterion requires that petitioner has "[n]o history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection." 42 C.F.R. § 100.3(c)(10)(i). While petitioner suffered from arthritis, degenerative joint disease with pain, and osteoporosis and her medical records are replete with complaints of joint pain, there is no specific complaint of "pain, inflammation or dysfunction" of her left shoulder prior to her receipt of the subject flu vaccine. *See generally* Pet. Ex. 2 at 4, 6, 30, 32, 35, 40, 50, 54; Pet. Ex. 6 at 18, 28-29; Pet. Ex. 7 at 15, 18; Pet. Ex. 15; Pet. Ex. 20. Therefore, petitioner satisfied the first criterion.

The third criterion requires that "[p]ain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered." 42 C.F.R. § 100.3(c)(10)(iii). As discussed in detail and determined in the Ruling on Onset, petitioner did not experience pain or

limitations with driving, dressing, or sleeping on her left shoulder until she had the onset of severe pain in March 2017: "I was not debilitated from the arm right after the flu shot. I was just in soreness and weakness" until months later. Tr. 47-50, 62-63, 65, 67, 131-34; Ruling on Onset, ECF No. 51. Further, when petitioner presented to Dr. Sherman on April 18, 2017, an examination of her left arm and shoulder was relatively normal, with 170 degrees of forward flexion and abduction, 60 degrees of external rotation, and 5/5 strength in all planes.[17] Pet. Ex. 3 at 14. However, by the time petitioner presented to physical therapy on May 16, 2017, she reported 9/10 shoulder pain and at her next medical visit on May 18, 2017, her passive range of motion was 102 degrees on abduction, a dramatic reduction of range of motion from a month prior. Pet. Ex. 5 at 4, 6. On June 26, 2017, she reported difficulty dressing secondary to shoulder pain and reduced range of motion. *Id*. at 5. By August 16, 2017, petitioner had full range of motion, external rotation of 45 degrees, and 4/5 strength. Pet. Ex. 21 at 5; Pet. Ex. 14; Pet. Ex. 3 at 5. Based on the record, petitioner did not suffer from pain or reduced range of motion until months after her vaccination, in March and May 2017, respectively.[18]

Further, petitioner described pain that radiated from her left shoulder to her upper arm and hand. Tr. 92-93, 119; Pet. Ex. 5 at 4, 5. Reports of pain in other locations, such as a petitioner's lower arm, hand, neck, or back are often considered in determining whether a petitioner satisfies this criterion. *See Werning v. Sec'y of Health & Human Servs.,* No. 18-0267V, 2020 WL 5051154, at *7 (Fed. Cl. Spec. Mstr. July 27, 2020); *Cross v. Sec'y of Health & Human Servs*., No. 19-1958V, 2023 WL 120783, at *7 (Fed. Cl. Spec. Mstr. Jan. 6, 2023); *K.P. v. Sec'y of Health & Human Servs*., No. 19-0065V, 2022 WL 3226776, at *8 (Fed. Cl. Spec. Mstr. May 25, 2022). However, even if it was determined that petitioner's pain and reduced range of motion were limited to her left shoulder to satisfy part (iii), by her own admission petitioner did not have onset of pain within 48 hours and therefore cannot satisfy the SIRVA requirements.

Finally, the fourth criterion requires that "[n]o other condition or abnormality is present that would explain the patient's symptoms (e.g NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy)." 42 C.F.R. § 100.3(c)(10)(iv). An MRI on July 5, 2017 revealed a complete full thickness supraspinatus tendon tear with proximal tendon retraction to the level of the acromioclavicular joint with mild fatty replacement of the muscle; full thickness tear of the anterior two thirds of the infraspinatus with proximal tendon retraction to the level of the acromion; high-grade partial thickness articular sided tear of the posterior third of the infraspinatus; and subscapularis tendinosis with superior articular sided fibers fraying. Pet. Ex. 8 at 5. The findings were consistent with subacute/chronic Hill-Sachs impaction fracture deformity and bony Bankart Lesion. There was large glenohumeral joint effusion/synovitis with free communication to the subacromial bursa via the full thickness rotator cuff tears and acromioclavicular joint osteoarthritis. The findings were suggestive of a near full-thickness avulsion tear of the long head of the biceps from the glenoid insertion with proximal

[17] Normal shoulder flexion for adults ranges from 165 to 180 degrees, and normal abduction for adults varies from about 170-180 degrees. Cynthia C. Norkin and D. Joyce White, MEASUREMENT OF JOINT MOTION: A GUIDE TO GONIOMETRY 72, 80 (F. A. Davis Co., 5th ed. 2016).

[18] It has previously been determined that part (ii) of the QAI requires that pain must occur within 48 hours of vaccination, but there is not a defined time period for the onset of reduced range of motion. *Bolick v. Sec'y of Health & Human Servs*., No. 20-893V, 2023 WL 8187307, at *7 (Fed. Cl. Spec. Mstr. Oct. 19, 2023) (citing *Robuck v. Sec'y of Health & Human Servs*., No. 20-0465V, 2023 WL 6214986, at *6 (Fed. Cl. Aug. 21, 2023).

tendon retraction into the mid to distal arm. *Id*. When Dr. Sherman reviewed the MRI results, his impression was "[i]rreparable rotator cuff tear." Pet. Ex. 21 at 6; Tr. 89-90, 95-96.

Succinctly, and as argued by respondent, the MRI findings "revealed many changes unrelated to an inflammatory reaction from vaccination." Resp. Rpt. at 7, ECF No. 21. The findings are not consistent with receipt of a vaccination that felt different and caused soreness until five months later, when there was an abrupt onset of severe pain. Petitioner failed to satisfy part (iv) of the QAI.

B. Causation In Fact

Having failed to satisfy the Table SIRVA requirements, petitioner must prove causation in fact by satisfying the three-pronged test set forth in *Althen* by the preponderance of evidence standard required in the Vaccine Act. 418 F.3d at 1278.

Petitioner did not plead an off-Table claim. She did not present any evidence to show that she sustained a defined injury to her left arm and/or shoulder that was related to the October 28, 2016 flu vaccine, or that the onset of her severe pain in March 2017 developed within a time for which an inference of causation is appropriate. Therefore, petitioner failed to provide any support for *Althen* Prongs.

VI. Conclusion

Upon careful evaluation of all the evidence submitted in this matter, I find that petitioner has not shown by preponderant evidence that her vaccination caused the injury alleged. Thus, petitioner may not receive compensation under the Vaccine Act. **The Clerk shall enter judgment accordingly.**[19]

IT IS SO ORDERED.

s/ Mindy Michaels Roth
Mindy Michaels Roth
Special Master

[19] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party filing a notice renouncing the right to seek review.